Exhibit 85

UNITED STATES DISTRICT COURT
FOR THE
DISTRICT OF SOUTH CAROLINA
COLUMBIA DIVISION

TAP PHARMACEUTICALS, INC.,
2355 Waukegan Road
Deerfield, IL 60015,

Plaintiff,

v.

UNITED STATES
DEPARTMENT OF HEALTH AND
HUMAN SERVICES,
200 Independence Avenue, S.W.
Washington, D.C. 20201,

HEALTH CARE FINANCING
ADMINISTRATION,
200 Independence Avenue, S.W.
Washington, D.C. 20201,
and

PALMETTO GOVERNMENT
BENEFITS ADMINISTRATORS,
Post Office Box 100190
Columbia, S.C. 29202, Carrier

Defendants.

3 97 969 19

Civil Action No.

COMPLAINT FOR DECLARATORY AND INJUNCTIVE RELIEF

Plaintiff TAP Pharmaceuticals, Inc. ("TAP"), by and through its attorneys, alleges as follows:

PRELIMINARY STATEMENT

This action involves a claim for injunctive and declaratory relief by TAP, a drug manufacturer located in Illinois, against defendants, the United States Department of Health and Human Services ("HHS"), the Health Care Financing Administration ("HCFA"), and Palmetto Government Benefits Administrators ("Palmetto"), the Medicare Part B Carrier located in South Carolina. The action arises out of arbitrary, capricious, and otherwise illegal action by defendants in basing the reimbursement amount for TAP's drug Lupron® upon the reimbursement amount for Zoladex®, a drug with a different method of administration, rate of action, and safety profile from those of Lupron®. TAP's specific claims are that defendants (1) committed acts contrary to law; (2) engaged in rulemaking without notice and comment and without other necessary procedures; and (3) engaged in arbitrary and capricious action. TAP seeks declaratory and injunctive relief pursuant to 5 U.S.C. § 706(2) and 28 U.S.C. § 2201.

JURISDICTION

APA Fed Question

1. This Court has jurisdiction over this action pursuant to 5 U.S.C. § 702 and 28 U.S.C. §§ 1331 and 2201(a). dwl jmt

2. Venue is proper in this district pursuant to 28 U.S.C. § 1391(b)(2). ?

THE PARTIES

3. Plaintiff TAP is a corporation organized and existing under the laws of Delaware with its principal place of business in Deerfield, Illinois. The primary business of TAP, a joint venture of Abbott Laboratories and Takeda Chemical Industries, Ltd., is the development and manufacture of the drugs Lupron®, for the treatment of advanced prostate cancer, and Prevacid®, for the treatment of duodenal ulcers.

4. Defendant HHS is a federal department located at 200 Independence Avenue, S.W., Washington, DC 20201.

5. Defendant HCFA is an agency within HHS, located at 200 Independence Avenue, S.W., Washington, DC 20201.

6. Defendant Palmetto is the Medicare Part B Carrier located in South Carolina. On information and belief, Palmetto is a corporation organized and existing under the laws of South Carolina.

STATEMENT OF CLAIM

7. Palmetto has announced that beginning May 10, 1997, contrary to HCFA regulations, policies, and longstanding practice, it will no longer reimburse for Lupron® pursuant to the duly promulgated regulations for reimbursement for drugs provided to patients incident to a physician's service, but instead will reimburse for Lupron® based upon the reimbursement rate for Zoladex®. Palmetto's action violates federal statutes, regulations, and policies, and is based on a false, arbitrary, and capricious finding that there is no demonstrable difference in clinical efficacy between Lupron® and Zoladex®. Unless enjoined, Palmetto's action will have far-reaching ramifications for cancer patients who currently depend on the availability of Lupron®, and will irreparably injure TAP's business and reputation.

Background

8. The Social Security Act provides for Medicare reimbursement of "items or services [that] are...reasonable and necessary for the diagnosis or treatment of illness or injury, or to improve the functioning of a malformed body member." 42 U.S.C. § 1395y(a)(1)(A).

9. HCFA has interpreted the terms "reasonable and necessary" to mean "safe, effective, and widely accepted in the medical community." 54 Fed. Reg. 4302, 4308 (Jan. 30, 1989)

(preamble to proposed rule). A drug is considered "safe and effective" if the drug has been approved by the Food and Drug Administration ("FDA"), and the particular use is either approved by the FDA or supported by accepted medical practice, the standard compendia, or other authoritative medical literature. Medicare Carriers Manual (CCH), pt. 3 ("MCM") § 2049.4. The "reasonable and necessary" inquiry historically has not permitted carriers to take into account the cost of drugs.

10. The amount of Medicare's payment for drugs furnished incident to physician services is determined by 42 C.F.R. § 405.517, a regulation that sets out the standard methodology for payment for drugs. There are different payment calculations for the two different types of drugs: single-source and multiple-source drugs. For single-source drugs, such as Lupron®, the regulation provides that payment will be made based on the lower of the average wholesale price or estimated acquisition cost (as determined by surveys) of "the drug" at issue. 42 C.F.R. § 405.517(b).

11. Payment for multiple-source drugs, such as drugs for which the FDA has made a determination of equivalence, is based on the lower of the average wholesale price or the median price for all sources of the generic form of the drug. Id. § 405.517(c). Thus, HCFA has a policy for payment in situations where there are less costly "alternatives" to the drug at issue. Upon information and belief, the FDA has made no such finding of therapeutic equivalence in the case of Lupron® and Zoladex®, and the drugs in question do not contain the same chemical entity.

12. With respect to the "reasonable and necessary" inquiry set out in the Social Security Act, HCFA has set a different reasonableness standard for durable medical equipment ("DME") in § 2100 of the MCM. DME is defined as equipment that can withstand repeated use, is

primarily and customarily used to serve a medical purpose, generally is not useful to a person in the absence of illness or injury, and can be used in the home. MCM § 2100.1. As part of determining reasonableness for DME reimbursement, carriers are instructed to consider the comparative costs of "medically appropriate and realistically feasible alternative pattern[s] of care," and the MCM states that where a less costly alternative is available, "payment should be based on the reasonable charge for this alternative." MCM § 2100.2(B).

13. Another section of the MCM, titled "Development of MR [Medical Review] Policy—General," informs carriers that for DME claims, they should use the "least costly alternative" criterion. This section then states, in a single sentence without further elaboration, that the carrier has "the discretion to apply this principle to payment for non-DME items and services as well." MCM § 7501.1(C).

14. In January 1989, HCFA proposed the idea of allowing carriers to use cost as a factor in making coverage determinations as part of its "reasonable and necessary" determination under section 1861 of the Social Security Act, which would have applied to coverage of drugs. 54 Fed. Reg. 4302 (Jan. 30, 1989). However, in the eight years since it was proposed, this rule has never been made final. Certainly, no such policy was in effect when Palmetto made its arbitrary determination to take cost into account when setting the reimbursement rate for Lupron®.

Reimbursement for Lupron®

15. Lupron® is a drug administered by intramuscular injection (injection of liquid directly into the muscle tissue) to treat prostate cancer. It is both reasonable and necessary to use Lupron® in treating certain patients in the final stages of prostate cancer. Accordingly, for over five years, and consistent with HCFA regulations, Palmetto and all other carriers across

the country have reimbursed patients for the average wholesale price of Lupron® consistent with 42 C.F.R. § 405.517(b).

16. In a bulletin dated October 1996, Palmetto announced an unprecedented policy change: beginning November 1, 1996, Palmetto would reimburse physicians who administer Lupron® only up to the average wholesale price of a competitor's product, Zoladex®. The only explanation offered for this change in policy was the conclusory, unsupported, and erroneous statement that "there is no therapeutic difference between these two agents." Palmetto Gov't Benefits Adm'rs, Medicare Advisory, Oct. 1996, at 32. Some physicians did not receive this bulletin until the middle of October, giving them only ten working days to prepare for this change in policy. Palmetto subsequently acknowledged its error in making this statement, by issuing a new policy that took into account the greater duration of action of Lupron®. Palmetto Gov't Benefits Adm'rs, Medicare Advisory, Nov. 1996, at 28.

17. Following a transparently inadequate effort to comply with local medical review policy procedures, Palmetto this month published a notice announcing that the new policy will take effect on May 10, 1997. This notice incorrectly stated that "there is no demonstrable difference in clinical efficacy" between Lupron® and Zoladex®. Palmetto Gov't Benefits Adm'rs, Medicare Advisory, Apr. 1996 ("April Advisory"), at 38.

18. Reimbursing for Lupron® at the Zoladex® level is not sufficient to cover some physicians' cost of providing Lupron® to their patients, particularly given that some patients are unable to make the required co-payment for Medicare drugs. By contrast, the Zoladex® reimbursement amount more than covers physicians' cost of administering that drug. To date, many physicians who have been administering Lupron® to their patients have informed TAP that they will continue to administer Lupron® for a short period of time while TAP seeks relief from

the new policy. Unless this reimbursement policy is enjoined, however, many physicians who currently administer Lupron® will be forced to switch to Zoladex®, despite the detrimental impact on their patients.

19. The most recent notice containing Palmetto's change in policy provided no support for the carrier's determination that "there is no demonstrable difference in clinical efficacy" between the two products. Upon information and belief, the vast number of physicians, including the urologist member of the Carrier Advisory Committee, who responded to the notice opposed the implementation of this policy. Also upon information and belief, Palmetto's determination that there is no clinical difference between Lupron® and Zoladex® was not based on any scientific evidence or clinical study that compared the two drugs. In fact, Lupron® and Zoladex® are not "equivalents" as that term is used by the FDA or "multiple-source drugs" as that term is used by HCFA in the payment regulation. The carrier's determination that there is no therapeutic difference between the drugs is not supported by any clinical evidence and is arbitrary and capricious.

20. Because of the differences in the two drugs and the manner in which they are administered, the physicians' switch from Lupron® to Zoladex® would have a drastic effect on patient care. The drugs have different rates of action, and the different formulations implicate different adverse reactions, administration techniques, and other factors. For example, the two products have different dosing regimens and expose patients to different risks in the event that the patients are delayed in obtaining their regular injections.

21. The methods of administering Lupron® and Zoladex® differ dramatically. Lupron® is administered in the form of a liquid suspension containing microspheres that release the active drug, leuprolide, steadily over one to three months. Zoladex®, in contrast, is a pellet the size

of a grain of rice that must be injected under the skin. Therefore, the two products require different gauge needles: thin 22-gauge needles for Lupron®, and large-bore 14- and 16-gauge needles for Zoladex®. An abdominal implant inserted with a 14- or 16-gauge needle is more likely to cause occasional complications for patients, such as keloid scarring and bleeding hematoma. Keloid scarring is particularly common among African-American men, in which population the incidence of prostate cancer is significantly greater than in Caucasian males.

22. Due to the invasiveness of and discomfort caused by the Zoladex® injection, the Zoladex® package insert suggests that, at the physician's or patient's option, a local anesthetic and bandage be used when injecting the pellet. Lupron®, which is administered through a simple intramuscular injection of liquid, does not require these additional procedures. In addition, the Zoladex® package insert states: "If the hypodermic needle penetrates a large vessel, blood will be seen instantly in the syringe chamber." These and other factors have caused a distinct difference in levels of patient acceptability of the two drugs.

23. In its most recent notice, Palmetto states: "[S]ince there is a difference in patient comfort between the two agents, Medicare will allow an additional beneficiary payment. The beneficiary may be charged up to the price difference between the least [sic] costly and the more costly medication." In fact, under the Medicare statute, physicians who accept assignment of Medicare claims may charge a beneficiary only the amount that Medicare allows for a covered physician service, including the cost of drugs administered incident to a physician service. Other physicians may charge an additional amount—above the Medicare-allowed amount—only if the additional charge does not exceed the difference between 95% and 115% of the allowable amount for the service. 42 U.S.C. §§ 1395u(b)(3)(B)(ii), 1395w-4(g). If physicians and

patients follow the instructions set out in Palmetto's notice, the physician could be subjected to sanctions for violation of the participation agreement or Medicare limiting-charge provisions.

24. The notice also contains an erroneous and seriously prejudicial statement that Medicare does not cover Lupron®. In a "Sample Advanced Beneficiary Notice," the bulletin states that if a service "is 'not reasonable and necessary' under Medicare program standards, Medicare will deny payment for Lupron®. Medicare will pay for Zoladex®." The clear import of this statement is that Lupron® is not a covered service under Medicare, even though Lupron® is an FDA-approved drug and its effectiveness in treating advanced prostate cancer is reflected in its labeling. The bulletin statement is seriously prejudicial to TAP in that it could lead physicians and patients to conclude that treatment involving Lupron® is not reasonable and necessary and will not be covered by Medicare.

25. Despite the state effective date of the new policy, May 10, 1997, Palmetto has already begun partially denying reimbursement for Lupron® claims. In March, a South Carolina urologist applied to Palmetto for reimbursement for three-month injections of Lupron® administered in March and was told that the third month of the injection was not covered because Palmetto's new policy would take effect May 10, before the end of the three-month period in which this injection would be effective. In other words, these patients were required to pay the full cost of a month's worth of Lupron®—not merely the cost difference between Lupron® and Zoladex® for that month—long in advance of the stated effectiveness date of this policy.

26. TAP will suffer irreparable harm unless this Court declares defendants' actions illegal and enjoins them from enforcing Palmetto's reimbursement limitation. TAP has longstanding relationships with physicians, many of whom are likely to switch from Lupron®

to Zoladex® when confronted with the drastically different reimbursement rates, simply in order to avoid economic harm by prescribing Lupron®. This switch is likely to injure TAP's business and reputation and to cause financial losses that are irreparable, incalculable, and not easily ascertainable.

27. Many physicians who will have switched to Zoladex® during the pendency of the case will be unlikely to switch back to Lupron®, for fear of alienating their patients with repeated changes in treatment. Moreover, physicians who switch from Lupron® to Zoladex® for their Medicare patients are likely to make the same switch for their other prostate cancer patients, because manufacturers of both drugs provide volume discounts, and physicians typically keep either Lupron® or Zoladex®, but not both, in inventory.

28. Moreover, the patients themselves will suffer harm from Palmetto's decision in that patients of physicians who switch to Zoladex® will have to undergo the more painful and invasive pellet injection required for the delivery of that drug. The switch in physician prescriptions from Lupron® to Zoladex® will further harm TAP's reputation for producing a dependable and well-received product.

29. TAP wrote to Donna E. Shalala, the Secretary of HHS, on or about February 18, 1997; to Thomas A. Ault, the Director of the Bureau of Policy Development at HCFA, on or about December 13, 1996; to Patricia Talley, the Acting Regional Director of HCFA, on or about January 22, 1997; and to Dr. David P. Sheridan, the Medical Director of Palmetto, on or about January 21 and March 19, 1997, to explain the foregoing matters, to ask that the new policy be rescinded, and to warn these parties that without rescission of the new policy TAP would be forced to take legal action. The defendants refused to rescind these illegal policies, thereby causing TAP to file this action.

COUNT I

(Action Violating Agency Regulations)

30. The allegations contained in paragraphs 1-29 are incorporated herein by reference.

31. HHS regulations state that Medicare payment for a covered single-source drug provided as part of a physician's services must be "based on the lower of the estimated acquisition cost or the national average wholesale price of the drug." 42 C.F.R. § 405.517(b) (emphasis added).

32. Palmetto's change in policy, purporting to authorize reimbursement for Lupron® based not on the average wholesale price of that drug but on the average wholesale price of a different drug, violates 42 C.F.R. § 405.517(b).

33. HHS and HCFA have failed to rescind the illegal actions of Palmetto, their agent.

34. The Administrative Procedures Act ("APA") requires a court reviewing agency action to set aside actions found to be arbitrary, capricious, an abuse of discretion, or otherwise not in accordance with law. 5 U.S.C. § 706(2).

35. As a proximate result of defendants' violations, TAP has suffered and will continue to suffer damages in the form of lost customers, income, and market share, and injury to its business reputation. TAP has no effective remedy under law that would provide the proper measure of damages.

COUNT II

(Action Violating Notice-and-Comment Provisions of Administrative Procedure Act and the Social Security Act)

36. The allegations contained in paragraphs 1-35 are incorporated herein by reference.

37. The APA and the Social Security Act provide that an agency may promulgate a substantive rule only after interested parties receive notice of the proposed rule and have adequate opportunity to provide comments. 5 U.S.C. § 553; 42 U.S.C. § 1395hh(a)(2), (b).

38. Palmetto's new policy is a substantive rule in that it imposes obligations; produces significant effects on TAP, physicians and patients; sets a conclusive, binding standard; and attempts to amend prior substantive law by ending Palmetto's practice of reimbursing patients for the average wholesale price of Lupron®. Palmetto did not subject this policy to notice-and-comment procedures.

39. Medicare Carriers Manual § 7501.1(C), which Palmetto alleges allows for reimbursement of non-DME items based on the least costly alternative, imposed obligations, produced significant effects on TAP, physicians, and patients, and amended prior substantive law to the extent that HHS, HCFA, or Palmetto construes this provision to allow consideration of cost in drug coverage and reimbursement decisions.' HCFA did not subject this policy to notice-and-comment procedures.

40. The APA requires a court reviewing agency action to "hold unlawful and set aside agency action, findings, and conclusions found to be . . . without observance of procedure required by law." 5 U.S.C. § 706(2)(D). Because HCFA did not follow the procedures required by 5 U.S.C. § 553 prior to promulgating this policy, this Court must hold the policy unlawful and set it aside.

41. HHS has failed to rescind the illegal actions of HCFA and Palmetto, its agents.

42. As a proximate result of these statutory violations, TAP has suffered and will continue to suffer damages in the form of lost customers and income and injury to its business

reputation. Apart from this action, TAP has no effective remedy under law that would provide the proper measure of damages.

COUNT III

(Arbitrary and Capricious Agency Action)

43. The allegations contained in paragraphs 1–42 are incorporated herein by reference.

44. Palmetto has implemented a policy of reimbursing physicians who administer Lupron® only up to the average wholesale price of Zoladex®, based on the erroneous ground that "there is no therapeutic difference between these two agents."

45. In fact, there are several important therapeutic differences between Lupron® and Zoladex®. The drugs have different rates of action, and the different formulations implicate different adverse reactions, administration techniques, and other factors.

46. Palmetto's policy statement of April 1997 was arbitrary and capricious in that it was based not on any scientific evidence or clinical study that compared the two drugs but on the conclusory, unsupported, and erroneous statement that there is no therapeutic difference between these two agents.

47. HHS and HCFA have failed to rescind the arbitrary and capricious actions of Palmetto, their agent.

48. The APA requires a court reviewing agency action to set aside action found to be arbitrary, capricious or an abuse of discretion. 5 U.S.C. § 706(2).

49. As a proximate result of this violation, TAP has suffered and will continue to suffer damages in the form of lost customers and income and injury to its business reputation. Apart from this action, TAP has no effective remedy under law that would provide the proper measure of damages.

COUNT IV

(Agency Action Violating Social Security Act)

50. The allegations contained in paragraphs 1–49 are incorporated herein by reference.

51. The Social Security Act provides for Medicare reimbursement of "items or services [that] are...reasonable and necessary for the diagnosis or treatment of illness or injury, or to improve the functioning of a malformed body member." 42 U.S.C. § 1395y(a)(1)(A).

52. By issuing its policy of April 1997, which added a cost component to the "reasonable and necessary" standard, Palmetto violated 42 U.S.C. § 1395y(a)(1)(A).

53. To the extent that MCM § 7501.1(C) purports to add a cost component to the "reasonable and necessary" standard, HCFA has also violated 42 U.S.C. § 1395y(a)(1)(A) in promulgating MCM § 7501.1(C).

54. HHS has failed to rescind the illegal actions of HCFA and Palmetto, its agents.

55. The APA requires a court reviewing agency action to set aside action found to be arbitrary, capricious, an abuse of discretion, not in accordance with law, or in excess of statutory jurisdiction, authority, or limitations, or short of statutory right. 5 U.S.C. § 706(2).

56. As a proximate result of Palmetto's and HCFA's violations, TAP has suffered and will continue to suffer damages in the form of lost customers, income, and market share, and injury to its business reputation. TAP has no effective remedy under law that would provide the proper measure of damages.

DEMAND FOR JUDGMENT

WHEREFORE, TAP prays that this Court enter judgment and grant other relief against defendants as follows:

(1) A declaration, pursuant to 28 U.S.C. § 2201(a), that the defendants' actions violated the laws of the United States and the regulations and policies of HCFA;

(2) Permanent injunctive relief against defendants from implementing the policy of authorizing or providing reimbursement for Lupron® based on the reimbursement amount determined for Zoladex®; and

(3) Issuance of such other and further relief as the Court may deem just and proper.

Respectfully submitted,
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April 9, 1997

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UNITED STATES DISTRICT COURT
FOR THE
DISTRICT OF SOUTH CAROLINA
COLUMBIA DIVISION

APR 1 0 1997

LARRY W. PROPES, CLERK
COLUMBIA, S. C.

TAP PHARMACEUTICALS, INC.,
2355 Waukegan Road
Deerfield, IL 60015,

Plaintiff,

v.

UNITED STATES
DEPARTMENT OF HEALTH AND
HUMAN SERVICES,
200 Independence Avenue, S.W.
Washington, D.C. 20201,

HEALTH CARE FINANCING
ADMINISTRATION,
200 Independence Avenue, S.W.
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PALMETTO GOVERNMENT
BENEFITS ADMINISTRATORS,
Post Office Box 100190
Columbia, S.C. 29202,

Defendants.

3 97 969 19

Civil Action No.

ANSWERS TO RULE 7.04 INTERROGATORIES

Pursuant to Rule 16 (b) of the Federal Rules of Civil Procedure and Rule 7.04 of the Local District Court Rules, the UNITED STATES DISTRICT COURT, Plaintiff, TAP PHARMACEUTICALS, INC., answers the Court's Rule 7.04 Interrogatories as follows:

(A) **Furnish a detailed factual basis for each claim you assert. If a contract, writing or document forms the basis of any claim, quote or attach the relevant portions, state your construction thereof and the claimed breach or wrongful conduct in connection therewith.**

ANSWER:

This action involves a claim for injunctive and declaratory relief by TAP, a drug manufacturer located in Illinois, against defendants, the United States Department of Health and Human Services ("HHS"), the Health Care Financing Administration ("HCFA"), and Palmetto Government Benefits Administrators ("Palmetto"), the Medicare Part B Carrier located in South Carolina. The action arises out of arbitrary, capricious, and otherwise illegal action by defendants in basing the reimbursement amount for TAP's drug Lupron® upon the reimbursement amount for Zoladex®, a drug with a different method of administration, rate of action, and safety profile from those of Lupron®. TAP's specific claims are that defendants (1) committed acts contrary to law; (2) engaged in rulemaking without notice and comment and without other necessary procedures; and (3) engaged in arbitrary and capricious action. TAP seeks declaratory and injunctive relief pursuant to 5 U.S.C. § 706(2) and 28 U.S.C. § 2201.

The above factual basis pertains to each of the four claims asserted in this action.

(B) **Describe, by name and citation or other generally recognized identification, decisions, statutes, ordinances, acts, codes, regulations, legal principles, standards, and customs or usages, which you contend are especially applicable to this Action[1]. State which jurisdiction's law applies to each claim and why.**

ANSWER:

As to COUNT I, 42 C.F.R. § 405.517(b) provides that Medicare payment for a covered single-source drug provided as part of a physician's services must be "based on the lower of the estimated acquisition cost or the national average wholesale price of the drug." Also, 5 U.S.C. § 706(2) [Administrative Procedures Act ("APA")] requires a court reviewing agency action to

[1] References to the general common, statutory or regulatory law of the relevant jurisdiction will not be deemed an adequate response.

set aside actions found to be arbitrary, capricious, an abuse of discretion, or otherwise not in accordance with law.

As to COUNT II, 5 U.S.C. § 553 [APA] and 42 U.S.C. § 1395hh(a)(2) and (b) of the Social Security Act provide that an agency may promulgate a substantive rule only after interested parties receive notice of the proposed rule and have adequate opportunity to provide comments. Also, 5 U.S.C. § 706(2)(D)[APA] requires a court reviewing agency action to "hold unlawful and set aside agency action, findings, and conclusions found to be . . . without observance of procedure required by law."

As to COUNT III, 5 U.S.C. § 706(2) [APA] requires a court reviewing agency action to set aside action found to be arbitrary, capricious or an abuse of discretion.

As to COUNT IV, 42 U.S.C. § 1395y(a)(1)(A) of the Social Security Act provides for Medicare reimbursement of "items or services [that] are...reasonable and necessary for the diagnosis or treatment of illness or injury, or to improve the functioning of a malformed body member." Also, 5 U.S.C. § 706(2) [APA] requires a court reviewing agency action to set aside action found to be arbitrary, capricious or an abuse of discretion.

The following laws pertain to the jurisdiction and venue issues for all claims in this action: 5 U.S.C. § 702; 28 U.S.C. §§ 1331 and 2201(a); 28 U.S.C. § 1391(b)(2).

(C) State the full names, addresses, and telephone numbers of all lay witnesses whose testimony you may use at the trial of this case and describe the special factual issues to which that testimony is expected to relate.

ANSWER:

The following lay witnesses may be used at the trial of the case:

1. Richard K. Masterson, 2355 Waukegan Road, Deerfield, Illinois, 60015, telephone (847) 937-5267, will testify regarding his knowledge of HHS, HCFA, and Palmetto's improper actions and their impact on physicians, patients and TAP.

2. Chris Lockett, 17411 Ryfield Court, Comus, Maryland 20842, telephone (301) 972-7525, will testify regarding his knowledge of HHS, HCFA, and Palmetto's improper actions and their impact on physicians, patients and TAP.

3. James Knott, 3675 River Summit Trail, Duluth, Georgia, 30155, telephone (770) 813-0837, will testify regarding his knowledge of HHS, HCFA, and Palmetto's improper actions and their impact on physicians, patients and TAP.

4. Thomas A. Ault, formerly at Health Care Financing Administration, 7500 Security Boulevard, Baltimore, Maryland 21233, telephone (410) 786-5635, will testify regarding his knowledge of HHS, HCFA, and Palmetto's improper actions.

5. Kathleen Buto, Health Care Financing Administration, 200 Independence Avenue, S.W., Washington, D.C. 20201, telephone (202) 690-7063, will testify regarding her knowledge of HHS, HCFA, and Palmetto's improper actions.

6. David P. Sheridan, Palmetto Government Benefits Administrators, Post Office Box 100190, Columbia, South Carolina, telephone (803) 735-1034, will testify regarding his knowledge of HHS, HCFA, and Palmetto's improper actions.

(D) Identify by full name, address, and telephone number each person whom you expect to call as an expert witness at the trial of this case, and, as to each expert so identified, state the subject matter on which he is expected to testify, the substance of the facts and opinions to which he is expected to testify, and a summary of the grounds for each opinion.

ANSWER:

It is anticipated that expert witnesses will be called in this action, but the exact identity of such individuals has not yet been determined. As soon as these expert witnesses are determined, amended Interrogatories will be filed with the court.

(E) If you contend that you have been injured or damaged, describe said injuries, damages and method of computation in detail, including but not necessarily limited to: the nature of the injury or damage; claimant's life expectancy; medical, nursing, hospital and similar expenses and the names of persons and institutions and the amount paid to and owing each; the cost of repairs to property and names of persons making them or, if incapable of repair, the value of the property immediately before the damage and immediately afterwards; the amount of lost earnings or profits; the period for which loss is claimed, and name the employer if applicable; the age, employment, earnings, marital status, and life expectancy of the deceased and the names, ages, and the relationship of each statutory beneficiary.

ANSWER:

Only Declaratory and Injunctive Relief are being sought by the Plaintiff at this time.

(F) **State the full name, address, and telephone number of all persons or legal entities who have a subrogation interest in each claim, and state the basis and extent of said interest.**

ANSWER:

None.

(G) **State the time you estimate it will take you to complete discovery. Explain if appropriate.**

ANSWER:

The Plaintiff anticipates utilizing interrogatories, request for production of documents, request for admissions, and taking numerous depositions. As soon as the answers to Defendant's standard interrogatories are received (in thirty (30) days), Plaintiff would anticipate initiating the discovery. The time period to conclude the initial discovery (interrogatories and request for production of documents) would take an additional sixty (60) days. Thereafter, an additional sixty (60) days would be needed to take the necessary depositions and conclude discovery, giving a total of one hundred fifty (150) days for discovery.

(H) **As to each claim, state whether it should be tried jury or nonjury and why.**

ANSWER:

It is requested that this be tried nonjury due to the issues and the nature of the relief being sought.

(I) **If the plaintiff is a publicly owned entity, or a partner, parent, subsidiary or affiliate of a publicly-owned entity, list the identity of the publicly owned entity and its relationship with the plaintiff. If there is a publicly-owned entity not a party to the case that has a significant financial interest in the outcome, identify such entity and the nature of the financial interest.**

ANSWER:

Plaintiff is a corporation organized and existing under the laws of Delaware with its principal place of business in Deerfield, Illinois and is a joint venture of Abbott Laboratories and Takeda Chemical Industries, Ltd.

(J) **State the basis for asserting your claim in the division in which it was filed.**

ANSWER:

Defendant Palmetto Government Benefits Administrators has its primary place of business and corporate operations within the Columbia Division.

(K) **Do you want a mediation conference to be scheduled in this case? If so, when? Do you object to mediation?[2] If so, why?**

ANSWER:

Plaintiff does not desire that a mediation conference be scheduled and objects to mediation on the basis that it is not appropriate to the resolution of this action. This action is brought by the Plaintiff to seek Declaratory and Injunctive Relief.

(L) **Do you, at this time, request or oppose an expedited trial under Local Rule 31.00? If so, include the information requested by that rule in these responses.**

ANSWER:

Plaintiff does not request an expedited trial under Local Rule 31.00 and would oppose same at this time.

(M) **If you are responding to a counterclaim, or other secondary claim, provide the information required by Local Rule 7.07(g).**

ANSWER:

Not applicable.

Respectfully submitted,

McNAIR LAW FIRM P.A.
M. Elizabeth Crum #372
Celeste T. Jones #2225
Edward L. Grimsley #5652
P.O. Box 11390
1301 Gervais Street
Columbia, S.C. 29211
(803) 799-9800

By: M. Elizabeth Crum
M. Elizabeth Crum

April 10, 1997

[2] See Rule 30.

ABBOTT LABORATORIES
Mark E. Barmak
Anni Goldberg
Office of General Counsel
Abbott Park, Illinois 60064
(847) 937-5267

HOGAN & HARTSON L.L.P.
Craig A. Hoover
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555 Thirteenth Street, N.W.
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VERIFICATION

PERSONALLY appeared before me TAP Pharmaceuticals, Inc. by and through Anni Goldberg, whose title is Counsel at Abbott Labs, who, first being duly sworn, says that s/he has read the foregoing TAP Pharmaceuticals, Inc.'s Answers to Rule 7.04 Interrogatories and, although s/he does not have personal knowledge of the facts stated therein, states they are true to the best of her/his information, knowledge and belief, and s/he verily believes them to be true and correct.

TAP Pharmaceuticals, Inc.

by: Anni Goldberg

SWORN TO BEFORE ME THIS
10th Day of April, 1997

Jackie A. Murphy (L.S.)
Notary Public for Illinois

My Commission Expires: 1/17/2001

"OFFICIAL SEAL"
JACKIE A. MURPHY
NOTARY PUBLIC, STATE OF ILLINOIS
MY COMMISSION EXPIRES 1/17/2001

COLA3:347167-1

UNITED STATES DISTRICT COURT
FOR THE
DISTRICT OF SOUTH CAROLINA
COLUMBIA DIVISION

TAP PHARMACEUTICALS, INC.,
2355 Waukegan Road
Deerfield, IL 60015,

Plaintiff,

v.

UNITED STATES DEPARTMENT OF HEALTH AND HUMAN SERVICES,
200 Independence Avenue, S.W.
Washington, D.C. 20201,

HEALTH CARE FINANCING ADMINISTRATION,
200 Independence Avenue, S.W.
Washington, D.C. 20201,
and

PALMETTO GOVERNMENT BENEFITS ADMINISTRATORS,
Post Office Box 100190
Columbia, S.C. 29202,

Defendants.

Civil Action No.: 3:97-969-19

CERTIFICATE OF SERVICE

I, Pamela W. Cox, do hereby certify that I have this date served one (1) copy of the Plaintiff's Summons and Complain and Plaintiff's Answers to Rule 7.04 Interrogatories upon the